

## Article 1. Definitions

### 1029.117. Medical Laboratory Technician.

“Medical laboratory technician” means a person who has completed education, training or experience, and examination requirements pursuant to Section 1032.5 (a), and who is authorized to perform clinical laboratory tests and examinations specified in Section 1032.5 (b).

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206, 1207, 1208, 1210, 1242, 1260.3, 1264, and 1300, Business and Professions Code.

1029.134. Practical Experience.

“Practical experience” means hands-on, direct work experience in clinical laboratory science and phlebotomy techniques on real patients in a clinical laboratory certified by CLIA, using equipment, instruments, kits and materials routinely found in clinical laboratories performing moderate or high complexity tests or examinations, and does not include work done in academic, research, forensic, pharmaceutical or veterinary laboratories.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206, 1208, 1222.5, 1242, 1242.5, 1243, 1246, 1260, 1260.3, 1261, 1261.5, 1264, 1269, and 1286, Business and Professions Code.

(1) Amend section 1031.8 to read:

1031.8. Conditions for Approval of a Certifying Organization to Administer a Certifying Examination for Licensure Purposes.

(a) In order for a certifying organization to be eligible for approval by the department to administer a category of certifying examination, the organization shall file a complete application that consists of the following:

- (1) Documentation that the certifying organization is a national, independent, not-for-profit, professional certifying organization; and
- (2) The organization's name and address; and
- (3) Names of the organization's officer(s) and board of directors; and
- (4) Description of the organization's structure and organizational chart; and
- (5) The identity of the person designated by the organization to be responsible for overseeing the administration and coordination of examination activities; and
- (6) A mission statement that demonstrates the philosophy of the certifying organization commits to an accurate assessment of a candidate's preparation in the clinical laboratory science category in which the candidate is examined; and
- (7) Schedule of dates that the examination will be available to California licensure applicants during the next four years; and
- (8) Listing of procedures for monitoring the content, quality, validity, reliability and relevance of the examination in the specialty being tested, and
- (9) Demonstration of how the organization's examination addresses the relevant standards in the clinical laboratory science category being examined, and how it

evaluates the knowledge and skills that would assure competence of the candidate; and

(10) Explanation of how the examination structure is developed by the organization, and the qualifications of person(s) who develop the examination questions; and

(11) Documentation that the organization's examination is subject to annual review for current relevance; and

(12) Demonstration of the ability of the organization to evaluate its examination, subjecting it to validity and reliability assessments using psychometric performance standards, and the capability of the organization to provide this information at least annually or upon request to the department; and

(13) Explanation of how the examination is developed and weighted using a job task survey to determine knowledge and skills required to be competent in the examination category; and

(14) Explanation of how examination questions are established, evaluated and updated to match current practice for the category; and

(15) Explanation of how the cutoff score for those successfully passing the examination is determined; and

(16) Documentation of performance statistics for the examination during the previous five years, including pass/fail rate, number of applicants and number accepted to the examination for each time that the examination has been administered by the certifying organization during the five years immediately prior to the date of application, or, for specialties that have been established for less

than five years, during the period dating from the establishment of the specialty to the date of the application; and

(17) Submission of printed copies of examinations given each year for the previous four years, if the examinations were offered. These examinations shall be subject to confidential review by the department, shall not be copied, and shall be returned to the organization; and

(18) Submission of an agreement to provide the examination to candidates who have been approved for admission to the examination by the department; and

(19) Submission of an agreement to provide verification of those persons successfully passing the examination to the department and to maintain these records for five years; and

(20) Submission of an agreement to give evidence of satisfactory performance as official notification to those passing the examination with the examinee's name, name of the certifying organization, examination category, effective date and official signature; and

(21) Demonstration how the organization will maintain security during development and administration of the examination, ensure the identity of the examinee, and maintain the confidentiality of the examination; and

(22) Listing of procedures in use and required of the organization's personnel to ensure security and confidentiality of the examination, and steps to be taken if a breach is discovered; and

(23) An agreement that a breach of security shall be reported to the department and that the department is authorized to investigate and withdraw approval of the examination category; and

(24) Documentation how the organization will make its records accessible to the department regarding those persons participating in the examination and their scores; and

(25) The name, title, and signature of the person who is responsible for overseeing the administration and coordination of all examination activities, and the date the application was signed.

(b) Initial approval of an organization's examination category shall include confidential review of an examination given each year up to four years immediately preceding the date of approval, so that examinations taken during this time shall be acceptable for licensure purposes.

(c) Timeframes for processing applications for approval of a certifying organization's examination in a clinical laboratory science category for licensure purposes shall be as follows:

(1) The department shall notify the applicant organization within 90 days of submission of an application of one of the following:

(A) That the application is complete and acceptable for processing by the department; or

(B) That the application is incomplete and not accepted for processing. This notification shall include the specific information or documentation that the

applicant shall submit within 30 days in order for the department to consider the application acceptable; or

(C) That the application has been reviewed and does not meet the requirements of this section and that approval is denied.

(2) The department shall consider an application to have been abandoned by any applicant who fails to respond to the department's request to submit specific information or documentation within 30 days of notification pursuant to Section 1031.8 (c)(1)(B).

(d) Written notification by the department to the applicant organization shall be considered to occur on the date the documents are postmarked,

(e) A certifying organization shall notify the department in writing of any change in the information and materials required by this section within 30 days after the change has occurred.

(f) Failure to meet and maintain the requirements of this section shall be good cause for denial or revocation of approval by the department.

NOTE: Authority cited: Section 1224, Business and Professions Code and Section 100275, Health and Safety Code.

Reference: Sections 1208, 1228, 1261, 1261.5, 1262, 1263 and 1264, Business and Professions Code.

(2) Amend section 1031.9 to read:

1031.9. Conditions for Renewal of a Certifying Organization's Approval to Administer Examinations Acceptable for Licensure Purposes.

(a) Approval of a certifying organization shall be valid for a period of four years unless revoked. At least 120 days prior to the end of the approval period, the certifying organization that wants to continue approval of its examination shall apply for reapproval. Failure to reapply 120 days in advance shall cause a lapse in approval after which time the examination would not be acceptable for licensure purposes until the certifying organization regains approval. A certifying organization that fails to reapply at least 120 days in advance and subsequently elects to seek approval shall make application pursuant to Section 1031.8.

(b) To apply for renewal of a certifying organization's approval to administer examinations, the organization shall provide the following:

- (1) The name and address of the certifying organization; and
- (2) Names of the organization's officer(s) and board of directors; and
- (3) Name of the person designated by the organization to be responsible for overseeing the administration and coordination of all examination activities; and
- (4) A schedule of dates that the examination will be available to California applicants during the next four years; and
- (5) A summary of the performance statistics of the examination during the previous approval period, including the number of California applicants applying



for, and successfully passing, the certifying examination, the applicant scores, what efforts have been made to evaluate the examination and update the examination questions to match current practice for the category; and

(6) The name, title and signature of the person responsible for overseeing the administration and coordination of all examination activities and date of application for renewal.

(c) The timeframes for processing an application of a certifying organization seeking renewal of its examination approval shall be as follows:

(1) The certifying organization shall submit an application for renewal of approval of its examination at least 120 days prior to the end of the approval period.

(2) Within 30 days of receipt of a renewal application, the department shall inform the organization in writing that the renewal application is complete and accepted for review, or deficient and what specific information or documentation is required to complete the application.

(3) Within 30 days of receiving a completed renewal application, the department shall inform the applicant organization in writing whether the examination has been reapproved or denied.

(d) Failure to meet and maintain the requirements of this section shall be good cause for denial of reapproval by the department.

NOTE: Authority cited: Section 1224, Business and Professions Code and Section 100275, Health and Safety Code.

Reference: Sections 1208, 1228, 1261, 1261.5, 1262, 1263 and 1264, Business and Professions Code.

(3) Amend section 1032.5 to read:

1032.5. Licensure of Medical Laboratory Technicians.

(a) In order to qualify for licensure as a medical laboratory technician, a person shall apply for a license pursuant to Section 1031.4 (b) and meet the following requirements:

- (1) Have successfully completed at least 60 semester (90 quarter) units from an accredited college or university. The coursework shall consist of at least 36 semester units of physical and biological sciences with an emphasis on applied clinical science. Coursework shall include 6 semester units of chemistry and 6 semester units of biology appropriate for transfer to a baccalaureate program in science, taken prior to, or concurrently with, training or experience; and
- (2) Have met the following training or experience requirements by documenting one of the following:

(A) Graduating from a medical laboratory technician training program accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS);  
or

(B) Graduating from a medical laboratory technician training program approved by the department pursuant to Section 1035.3; or

(C) Meeting admission requirements for a clinical laboratory scientist licensing examination, as determined by the department pursuant to Section 1032; or

(D) Completing a minimum of three years on-the-job practical experience within the previous five years, in a clinical laboratory outside California as a medical

laboratory technician, with evidence of satisfactory performance on an examination given by a certifying organization for medical laboratory technicians, performing tests in the specialties of chemistry, hematology, microbiology, and immunology. This work experience shall include at least 480 hours in each of these specialties and shall be documented by the laboratory director(s) of the laboratory(ies) employing the applicant pursuant to Section 1031.4 (b)(8); or

(E) Completing a minimum of three years on-the-job practical experience within the previous five years, in a clinical laboratory outside California as a clinical laboratory scientist, with evidence of satisfactory performance on an examination given by a certifying organization for clinical laboratory scientists, performing tests in the specialties of chemistry, hematology, microbiology, and immunology. This clinical laboratory scientist, also called medical technologist in some states, need not be California licensed pursuant to Business and Professions Code section 1204, but shall have work experience outside California of at least 480 hours in each of these specialties as documented by the laboratory director(s) of the laboratory(ies) employing the applicant pursuant to Section 1031.4 (b)(8); or

(F) Completing a minimum of three years on-the-job practical experience within the previous five years, as a medical laboratory technician or clinical laboratory scientist in a California physician office laboratory or in a laboratory owned and operated by the United States of America. This person shall have evidence of satisfactory performance on an examination given by a certifying organization for medical laboratory technicians or clinical laboratory scientists, respectively, and have performed tests in the specialties of chemistry, hematology, microbiology

and immunology. This work experience shall include at least 480 hours in each of these specialties, and shall be documented by the physician(s) directing the laboratory(ies) employing the applicant pursuant to Section 1031.4 (b)(8); and

(3) Have passed a written examination for medical laboratory technicians administered by a certifying organization for medical laboratory technicians approved by the department pursuant to Section 1031.8. The department shall, for licensure purposes, accept evidence of satisfactory performance on examinations taken within the four years previous to department approval of a certifying organization's medical laboratory technician examination. The applicant shall have also passed a separate written, self-administered examination on California clinical laboratory law provided by the department . This self-administered test shall accompany the application. A minimum passage rate of 70 percent shall be required.

(b) A licensed medical laboratory technician shall be authorized to:

(1) Perform tests and examinations classified as waived and moderate complexity by Centers for Disease Control and Prevention in the specialties of chemistry, including routine chemistry, urinalysis, endocrinology and toxicology; hematology including coagulation; microbiology, including bacteriology, mycobacteriology, mycology, parasitology and virology; and immunology, including syphilis serology and general immunology, with the exception of those moderate complexity tests requiring microscopy, or in the specialty of immunohematology.

- (2) Perform phlebotomy, but shall not perform skin tests for specific diseases pursuant to Section 1242 of the Business and Professions Code.
- (3) Perform tests and examinations under the supervision of a licensed physician and surgeon, or a doctoral scientist, clinical laboratory bioanalyst, clinical laboratory scientist, or clinical laboratory specialist licensed under Chapter 3. On-site supervision shall be required during the entire time the medical laboratory technician performs moderate complexity clinical laboratory tests or examinations. The ratio of medical laboratory technician to supervisor at the site of moderate complexity testing shall not exceed four to one.
- (4) Report test results and perform phlebotomy only after competency has been documented by the laboratory director pursuant to Section 1209 (e) of the Business and Professions Code.
- (5) Supervise Limited Phlebotomy Technicians or Certified Phlebotomy Technician Is.
- (c) The license application fee and license renewal fee for a medical laboratory technician shall be the same as the license application fee and license renewal fee for a clinical laboratory scientist pursuant to Section 1300 (c) and (e) of the Business and Professions Code.
- (d) A medical laboratory technician shall complete twelve hours of continuing education each year as a condition for renewal.

NOTE: Authority cited: Section 1224, Business and Professions Code and Section 100275, Health and Safety Code.

Reference: Sections 1202.5, 1204, 1206, 1206.5, 1208, 1209, 1210, 1242, 1260.3, 1261, 1275, 1300 and 1320, Business and Professions Code.

1035.3. Medical Laboratory Technician Training Program Standards.

(a) In order to be eligible for approval by the department, a medical laboratory technician training program shall be offered by either a:

- (1) California licensed clinical laboratory; or
- (2) Accredited college or university in the United States of America; or
- (3) United States of America military medical laboratory specialist program of at least 26 weeks duration; or
- (4) Laboratory owned and operated by the United States of America.

(b) The program director of a medical laboratory technician training program shall be a physician and surgeon licensed under Chapter 5, or a doctoral scientist, clinical laboratory bioanalyst, clinical laboratory scientist or clinical laboratory specialist licensed under Chapter 3. The program director shall be responsible for the content, quality and conduct of the training program and shall:

(1) Employ instructors who are physicians and surgeons licensed under chapter 5; doctoral scientists, clinical laboratory bioanalysts, clinical laboratory scientists, or clinical laboratory specialists licensed under chapter 3; medical laboratory technicians with five years practical experience licensed under Chapter 3; or public health microbiologists certified pursuant to Health and Safety Code Section 101160.

(2) Assure that training includes at least 26 weeks, consisting of at least 1040 hours, of instruction and practical experience in moderate complexity testing in chemistry, including routine chemistry, urinalysis, endocrinology and toxicology;

hematology, including coagulation; microbiology, including bacteriology, mycobacteriology, mycology, parasitology and virology; and immunology, including syphilis serology and general immunology. The training shall include at least 160 hours each in chemistry, hematology, microbiology and immunology.

(3) Provide didactic training in:

(A) Pre-analytical skills including phlebotomy, specimen processing, reagent preparation, and infection control, as specified in Section 1035.1 (e) and (f); and

(B) Analytical skills required for performing tests of waived or moderate complexity, including quality control, test calibration, quality assurance, legal requirements for documentation of testing, data storage and retrieval, safety and standard precautions, troubleshooting, preventive maintenance, reagent preparation and storage; and

(C) Post-analytical skills such as knowledge of factors that influence test results and the ability to access and verify the validity of patient test results through review of quality control values prior to reporting patient test results; and

(D) Test methods commonly used in chemistry, hematology, microbiology and immunology, including clinical significance of test results, how the tests interrelate and how the tests impact diagnosis and treatment, quality assessment of test results, information processing and regulatory compliance in state and federal law.

(4) Provide practical training in:

- (A) Phlebotomy that shall include 40 hours instruction and successful completion of a minimum of 10 skin punctures and 50 venipunctures, as specified in Section 1035.1 (f); and
  - (B) Instruction and practical experience in the use of instruments; and
  - (C) Preventive maintenance and problem solving malfunctions of instruments; and
  - (D) Knowledge of instrument and test parameters to assess reasonableness of results; and
  - (E) Validation of moderate complexity test methods and clinical correlation of test results.
- (c) A medical laboratory technician training program shall provide a certificate of completion to its students upon satisfactory completion of the program. The program shall maintain a copy of this certificate for at least five years. This certificate shall be signed by the director of the program and shall include:
- (1) Name and address of the training program; and
  - (2) Name of the student; and
  - (3) Statement of satisfactory completion of the program; and
  - (4) Dates that training began and ended.
- (d) A program approved to train medical laboratory technicians shall maintain records of its students for at least five years and shall make available to the department documentation of the students successfully completing their training.
- (e) A medical laboratory technician training program seeking approval from the



department shall provide documentation to substantiate that its program objectives meet training criteria stated in this section.

(f) A medical laboratory technician training program shall be allowed to document program compliance with the requirements of this section for a period dating up to four years prior to their initial application, after the date of implementation of these standards. The program shall document that, during the time preceding initial approval, the training program met the standards pursuant to Section 1035.3 (a) and (b).

(g) A complete application for a medical laboratory technician training program shall include the following:

- (1) The name and address of the primary training program, including city, state, county and zip code; telephone number, FAX number and e-mail address; and
- (2) The location(s) of all sites where training will be conducted, including city, state and zip code; and
- (3) The name(s) and qualifications of the person(s) directing and instructing in the program including a copy of current licensure for each person. Training programs in the United States of America but outside California shall provide evidence that the director(s) and instructor(s) substantially meet this licensure requirement by documenting inclusion, licensure or certification in a class of personnel similar to those required in Chapter 3 or requiring equivalent standards; and
- (4) Dates the training program was conducted if prior approval is requested as specified in Section 1035.3 (f); and

- (5) The didactic curriculum listing each class or topic with instructional objectives, the instructor(s) and the amount of time allocated for each class or topic, pursuant to Section 1035.3 (b)(3); and
  - (6) Documentation of practical training in pre-analytical, analytical and post-analytical skills, including instructor(s) and hours spent at each activity, list of equipment, supplies and materials used pursuant to Section 1035.3 (b)(4); and
  - (7) The signature(s) of the program director(s), telephone number(s) and date of application.
- (h) A medical laboratory technician training program approval shall be valid for a four-year period. To apply for renewal, the training program shall file an application at least 120 days prior to the end of the approval period providing the following:
- (1) The name and address of the primary training program, including city, state, county and zip code, telephone number, FAX number and e-mail address; and
  - (2) The name, address, and telephone number(s) of the director(s) and instructor(s), providing documentation of their current licensure; and
  - (3) Any changes in training locations, didactic and practical instruction, course objectives, equipment, supplies and materials, that shall be made to the program from that approved in the previous application; and
  - (4) A listing of all students who completed its program and the total number of students who enrolled in its program during the previous approval period; and
  - (5) The signature(s) of the program director(s) and the date of application for renewal.

- (i) The training program shall notify the department in writing of any change(s) in the information and materials required by Section 1035.3 (b) through (d) within 30 days after the change(s) has occurred.
- (j) Failure to meet and maintain the requirements of this section shall be good cause for denial or revocation of approval by the department.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.  
Reference: Sections 1206.5, 1208, 1209, 1222, 1222.5, 1242, 1246, 1260.3, 1269, 1286 and 1300, Business and Professions Code.

1035.4. Timeframes For Approval Of Training Programs.

(a) Timeframes for approval of training programs to train clinical laboratory personnel for licensure pursuant to Chapter 3 shall be as follows:

(1) Submission of an application for approval shall be deemed to occur on the date the application is received by the department.

(2) Written notification by the department to the applicant program shall be considered to occur on the date the documents are postmarked.

(3) The department shall notify the applicant within 60 days of submission of an application for training program approval, of one of the following:

(A) That the application is complete and acceptable for processing by the department; or

(B) That the application is incomplete and not accepted for processing. This notification shall include the specific information or documentation that the applicant shall submit within 30 days in order for the department to consider the application acceptable; or

(C) That the application has been reviewed and does not meet the requirements of this section and that approval is denied.

(4) The department shall consider an application to have been abandoned by any applicant program which fails to respond to the department's request to submit specific information or documentation within 30 days of notification pursuant to Section 1035.4 (a)(3)(B).

(b) Timeframes for processing applications for renewal of approval to train clinical laboratory personnel for licensure pursuant to Chapter 3 shall be as follows:

(1) The training program shall submit a renewal application at least 120 days prior to the end of the approval period.

(2) Within 30 days of receipt of a renewal application, the department shall inform the training program in writing that the application is complete and accepted for review, or deficient and what specific information or documentation is required to complete the application.

(3) Within 30 days of submitting a completed renewal application, the department shall inform the training program in writing whether its application has been approved or denied.

(4) The department may authorize a training program to extend its approval during the time its application is being reviewed when that training program is in good standing and its application was submitted at least 120 days prior to the end of the approval period.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.  
Reference: Sections 1261.5, 1263, 1264, 1286, and 1302 Business and Professions Code.